

Methylene Chloride: Small Entity Consultation on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Small Entity Representative Panel Outreach Meeting
January 28, 2021



Overview

- Consultation with Small Entity Representatives
- Overview of EPA's Rulemaking
- Key Takeaways from Pre-Panel Meeting
- Risk Management Requirements under TSCA
- Regulatory Options (Updated Information)
- Additional discussion with Small Entity Representatives
- Closing remarks



Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation
- Key elements in this analysis:
 - Number of small entities to which the potential rule would apply
 - Projected compliance requirements of the potential rule
 - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
 - Any significant alternatives to the potential rule which accomplish the stated objectives and which minimize significant economic impact of the potential rule on small entities



SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
 - Provide specific examples of impacts
 - Provide cost data, if available
 - Please see detailed questions in a separate handout
- We are also seeking alternative methods of regulating these risks
 - Suggest other relevant options, including data costs and information on how to ensure compliance
 - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
 - Provide information on any duplicative or contradictory Federal regulations you are aware of
 - For a list of existing regulations, please see summary of Federal regulations



Overview of EPA's Rulemaking

- See materials distributed for the Pre-Panel outreach meeting (Nov 5, 2020) for more detail on:
 - Findings from the risk evaluation
 - Conditions of use in the rulemaking
 - Basis for unreasonable risk determination
 - Risk management requirements under TSCA
 - EPA's authority and "tools in the toolbox"



Unreasonable Risk Determinations

- EPA determined that 47 of the 53 conditions of use of MC present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers and occupational non-users (ONUs) during occupational exposures
 - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute (central nervous system) and chronic (liver) inhalation and dermal exposure to MC
- Acute central nervous system effects were used to identify unreasonable risks because relatively small increases in exposure can range from central nervous system effects to more severe effects, including death



Key Takeaways from Pre-Panel Outreach Meeting

- Participants: 20 SERs participated and three SERs shared materials for discussion
- SERs discussed: Number and types of small entities affected
 - Included their own processing or use of methylene chloride, their customer base, and how their products are used
 - Specifically, SERs described
 - Polycarbonates manufacturing (medical, military, and other applications)
 - Chemical manufacturing (chemicals, pharmaceuticals, pesticides, processing agent)
 - Paint and coating removal (furnishing industry, antique restoration)
 - Degreasing and adhesives (brake and immersion cleaners, adhesives, automotive and specialty uses)



Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Potential reporting, recordkeeping and compliance requirements
 - SERs discussed their experience with:
 - Engineering controls (closed loop systems, ventilation apparatus, exhaust fans)
 - Administrative controls (SOPs, training, isolation, move on-site work to workplace)
 - PPE (air supplied respirators for equipment failure and maintenance), and support for PPE requirements
 - Combination of controls (engineering, administrative, and APF 50)
 - Monitoring and recordkeeping (including badge monitoring results below OSHA's methylene chloride PEL action level of 12.5 ppm)
 - Exposure limits generally
 - Labeling and container size for risk reduction



Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Substitution and the primary reasons methylene chloride is still in use
 - Advantages that were described:
 - Non-flammable alternatives are not as viable or as effective and are more costly
 - Flammable alternatives could increase insurance costs
 - Universal solvent (effectiveness, non-flammable, quick dry, and low odor)
 - A small molecule good for coating penetrants and degreasers
 - Long-lasting barrier to moisture and rust issues
 - Substitutes described (though not recommended)
 - Ethylene dichloride
 - Perchloroethylene (for degreasing)
 - Benzyl alcohol, methylated seed oil (MSO), n-Methylpyrrolidone (NMP)
- When considering potential substitute chemicals during this rulemaking:
 - For substitute chemicals with a completed risk evaluation, EPA will use the risk estimates to inform understanding of countervailing risks for relevant COUs
 - When final risk evaluations are not available, EPA will use a hazard comparison for potential chemical substitutes
 - EPA will incorporate input from SERs and other stakeholders regarding efficacy, feasibility, and other considerations



Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Related Federal rules
 - Focused on current OSHA requirements and exposure levels
 - SERs asked if EPA's regulatory action could be deferred to OSHA
- EPA and OSHA have ongoing dialogue in reference to risk management requirements under TSCA
 - EPA considered the OSHA PEL during the risk evaluation process, and identified an unreasonable risk below the levels in the PEL



Key Takeaways from Pre-Panel Outreach Meeting, cont.

- SERs discussed: Regulatory flexibility alternatives
 - SERs emphasized strong interest in knowing what level EPA might set for an ECEL
 - One SER stated that exposure reductions would be impractical when dealing with furniture refinishing
 - SERs provided recommendations regarding specific PPE (half-masks with goggles vs. full masks)
 - SERs stated that absence of a suitable substitute could result in high costs and production issues
 - Some SERs described the burdens of regulating closed loop systems, due to no way to close off the part of the system. SERs would like an exclusion for this use



Key Takeaways from Pre-Panel Outreach Meeting

- From written comments, information was provided on:
 - The amount of methylene chloride used by the firm
 - Alternatives SERs have tried and the success (or not) of those alternatives
 - Cost differentials of alternatives
 - Why methylene chloride is important to their specific use
 - Number of employees using methylene chloride
 - How SERs might adjust or respond if methylene chloride is no longer available
 - Potential feasibility of an ECEL



Critical or Essential Uses: TSCA Section 6(g)

Section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- To provide an exemption, EPA must find that:
 - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
 - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
 - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
 - Provide a time limit for the exemption.
 - Analyze the need for the exemption and make the analysis public.
 - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption



Effective Dates: TSCA Section 6(d)

- Section 6(d) describes effective dates and compliance dates for section 6(a) rules.
- In these rules, EPA must specify an effective date, which shall be as soon as practicable
- Except for uses exempted under section 6(g), EPA must:
 - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
 - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
 - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years (with a possible extension):
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule



TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase



Potential Regulatory Options

- EPA has considered a number of regulatory options under TSCA section 6(a), and considered a wide range of risk reduction practices and options
- Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures so that the conditions of use may no longer present an unreasonable risk
- These options are currently being considered and evaluated by EPA, and are not final at this time
- Regulatory options could be used alone or in combination so that methylene chloride no longer presents an unreasonable risk under any condition of use



Potential Regulatory Options, cont.

- EPA is seeking feedback on the impacts of applying one or more of the following regulatory options to the conditions of use of methylene chloride that present an unreasonable risk
- For processing, industrial, and commercial uses (occupational exposures):
 - Existing Chemical Exposure Limit (ECEL)
 - Establishes a performance-based airborne concentration limit and is non-prescriptive, enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace and the ability to combine prescriptive controls
 - Industries are already familiar with PELs, and methods of compliance. EPA and OSHA have ongoing dialogue in reference to risk management requirements under TSCA
 - ECEL would be 2 ppm (8 mg/m³) for an 8-hour time-weighted average (TWA)
 - STEL would be 16 ppm (57 mg/m³) as a 15-minute TWA



Potential Regulatory Options, cont.

- The value is based on the chronic non-cancer human equivalent concentration (HEC) for liver toxicity. This is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations
- At the 8-hour ECEL of 2 ppm, EPA expects that a worker would be protected against CNS depression as well as liver toxicity resulting from an acute (8-hour) exposure if ambient exposures are kept below this ECEL.
- The ECEL is above the limits of detection or quantification, which generally range from about 0.2 to 0.4 ppm
- EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health
- EPA is seeking feedback from the SERs on what current recordkeeping and monitoring is applied to the PEL and feedback on how to apply ECEL recordkeeping and monitoring based on current protocol.
- Potential ECEL guidance would include information on how appropriate respiratory protection varies with exposure levels. Example: OSHA's PEL and PPE (see Appendix slides)



Potential Regulatory Options, cont.

- For processing, industrial, and commercial uses (occupational exposures):
 - Prescriptive Controls: Engineering Controls
 - Would reduce worker or ONU exposure by requiring physical changes to the workplace
 - Examples: Require use of close-loop vapor degreasers, require specific ventilation rates, require spraying booths or laboratory hoods for laboratory applications, or isolate the work area where the methylene chloride is present
 - Prescriptive Controls: Administrative Controls
 - Would reduce worker or ONU exposure by requiring processes or procedures in the workplace
 - Examples: Limit access to work areas, control the number of hours workers are exposed to methylene chloride



Potential Regulatory Options, cont.

- Prescriptive Controls: PPE Controls
 - PPE was considered in the unreasonable risk determination and in some cases was insufficient to address unreasonable risk
 - Examples of potential regulatory option: Require use of APF of 1,000 or more; require that ONUs use PPE
- Prohibition
 - For conditions of use where ECEL or prescriptive controls are not sufficient to address the unreasonable risk



Potential Regulatory Options, cont.

- For consumer uses:
 - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers or bystanders
 - Example: March 2019 rule to address unreasonable risks to consumers from methylene chloride in paint and coating removal prohibited manufacture (including import), processing, and distribution in commerce of methylene chloride for this use (including distribution to and by retailers)
 - Potential regulatory options:
 - Concentration limit
 - Prohibition



Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
 - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
 - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
 - Monitoring – example: of air concentration to demonstrate compliance with ECEL
 - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
 - Limited access program – example: access only to those users with certain equipment, for example product only sold to facilities with close-loop vapor degreasers



Cost of Regulatory Options

| Option/Type of Cost | Estimated Compliance Cost | Notes |
|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Existing Chemical Exposure Limit (ECEL) | \$4,000 to \$7,400 daily monitoring fee \$200 to \$325 recordkeeping | ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates. |
| Engineering/Administrative Controls | Varies by control type and needs of user | Engineering controls are not expected to be a regulatory option used for methylene chloride. Admin controls are expected to have minimal costs, if any. An example would be a sign stating ONUs need to stay out of a given area, at a cost of \$10 per sign. |
| Reformulation of product to reduce or eliminate MC concentration (under Prohibition option) | \$13,000-\$129,000 per product Dilution: \$16,000 Standard: \$57,000 Complex: \$98,000 | Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. The breakdown shows generalized estimates but COU specific information, when available, may result in estimates being at the lower or upper end of the provided range. |
| Product Label or Warnings | \$750 - \$8,000 per product | Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. |



Cost of Regulatory Options, cont.

| Option/Type of Cost | Estimated Compliance Cost | Notes |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal Protective Equipment (PPE) – Inhalation exposure (respirators) | APF 25: \$1,200 APF 50: \$500-\$2,000 APF 1000: \$600-\$1,300 APF10000: \$1,700-\$2,000 See separate handout for detailed breakdown | Costs are per employee and include purchase of equipment (including filters), training, fit-testing, and medical clearance. Does not include existing PPE use nor PPE replacement due to employee turn-over. |
| Substitute Products (average per ounce) (under Prohibition option) | Example Prices (per ounce): Methylene Chloride: \$0.31 NMP: \$0.48 Caustic: \$0.22 Benzyl Alcohol: \$0.41 ATM: \$0.31 Dibasic Esters: \$0.40 TCE: \$0.38 PCE: \$0.30 Adhesive & Caulk Removers (off the shelf substitutes) \$0.31 to \$4.72 per ounce | Methylene chloride is expected to be less expensive per ounce than most substitutes, but the differences in efficacy of the substitute products is likely to be a more important factor for the costs of switching to using the substitute products. This list of substitute chemicals or off-the-shelf products is not exhaustive for all 47 COUs with unreasonable risk determinations. |



Cost of Regulatory Options, cont.

| Option/Type of Cost | Estimated Compliance Cost | Notes |
|--------------------------------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------|
| Substitute Methods (under Prohibition option) | Varies by job labor rate | This will primarily be labor cost and cost of alternative equipment (i.e., a heat gun). |
| Recordkeeping | \$200-\$325 per firm | Annual labor and material costs associated with documentation of ordinary business records. |
| Downstream Notification | \$112-\$125 per product | Costs are per product and include labor and material costs to update the product's safety data sheet (SDS). |



Additional Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives



Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
 - Written comments by February 11, 2021



Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- Risk Management Activities for MC: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>
- Methylene chloride: Ingrid Feustel (Feustel.ingrid@epa.gov, 202-564-3199)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)



Contact Information

- EPA SBAR contact: Lanelle Wiggins (Wiggins.lanelle@epa.gov)
- EPA Methylene chloride: Ingrid Feustel (Feustel.ingrid@epa.gov)
- SBA Advocacy: David Rostker (David.Rostker@sba.gov) and Tabby Zeb (Tayyaba.Zeb@sba.gov)
- OMB OIRA: Danielle Jones (Danielle_Y_Jones@omb.eop.gov) and Austin Mudd (Austin.B.Mudd@omb.eop.gov)



Appendix

- Conditions of Use:
 - Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk
 - Consumer Uses that Present an Unreasonable Risk
- Example: OSHA Respiratory Protection Table
- Key takeaways from Pre-Panel Outreach Meeting (separate document)
- Related regulations (EPA, other Federal, state, and international) (separate document)
- Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride (separate document)



Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Import
- Processing: Incorporation into formulation, mixture, or reaction products
- Processing: Repackaging
- Industrial and commercial use as solvent for batch vapor degreasing
- Industrial and commercial use as solvent for in-line vapor degreasing
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use in adhesives, sealants and caulks
- Industrial and commercial use in paints and coatings
- Industrial and commercial use in paint and coating removers
- Industrial and commercial use in adhesive and caulk removers
- Industrial and commercial use in metal aerosol degreasers
- Industrial and commercial use in metal non-aerosol degreasers
- Industrial and commercial use in finishing products for fabric, textiles and leather
- Industrial and commercial use in automotive care products (functional fluids for air conditioners)
- Industrial and commercial use in automotive care products (interior car care)
- Industrial and commercial use in automotive care products (degreasers)
- Industrial and commercial use in apparel and footwear care products
- Industrial and commercial use in spot removers for apparel and textiles



Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk, cont.

- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in spray lubricants and greases
- Industrial and commercial use in aerosol degreasers and cleaners
- Industrial and commercial use in non-aerosol degreasers and cleaners
- Industrial and commercial use in cold pipe insulations
- Industrial and commercial use as solvent that becomes part of a formulation or mixture
- Industrial and commercial use as a processing aid
- Industrial and commercial use as propellant and blowing agent
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing
- Industrial and commercial use for plastic and rubber products manufacturing
- Industrial and commercial use in cellulose triacetate film production
- Industrial and commercial use as anti-spatter welding aerosol
- Industrial and commercial use for oil and gas drilling, extraction, and support activities
- Industrial and commercial use in toys, playground and sporting equipment
- Industrial and commercial use in lithographic printing plate cleaner
- Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner



Consumer Uses that Present an Unreasonable Risk

- Consumer use as solvent in aerosol degreasers/cleaners
- Consumer use in adhesives and sealants
- Consumer use in brush cleaners for paints and coatings
- Consumer use in adhesive and caulk removers
- Consumer use in metal degreasers
- Consumer use in automotive care products (functional fluids for air conditioners)
- Consumer use in automotive care products (degreasers)
- Consumer use in lubricants and greases
- Consumer use in cold pipe insulation
- Consumer use in arts, crafts, and hobby materials glue
- Consumer use in an anti-spatter welding aerosol
- Consumer use in carbon removers and other brush cleaners



Example: OSHA Respiratory Protection Table

Minimum Requirements for Respiratory Protection for Airborne Methylene Chloride

| Methylene Chloride Airborne Concentration (ppm) or Condition of Use | Minimum Respirator Required |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Up to 625 ppm (25 X PEL) | Continuous flow supplied-air respirator, hood, or helmet |
| Up to 1,250 ppm (50 X PEL) | (1) Full facepiece supplied-air respirator operated in negative-pressure (demand) mode (2) Full facepiece self-contained breathing apparatus (SCBA) operated in negative-pressure (demand) mode |
| Up to 5,000 ppm (200 X PEL) | (1) Continuous flow supplied-air respirator, full facepiece (2) Pressure demand supplied-air respirator, full facepiece (3) Positive-pressure full facepiece SCBA |
| Unknown concentration, or above 5,000 ppm (Greater than 200 X PEL) | (1) Positive-pressure full facepiece SCBA (2) Full facepiece pressure (demand) supplied-air respirator with an auxiliary self-contained air supply |
| Firefighting | Positive-pressure full facepiece SCBA |
| Emergency Escape | (1) Any continuous flow or pressure-demand SCBA (2) Gas mask with organic vapor canister |